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Women's health chief quits over pill flap

FDA approval for over-the-counter sale of 'morning-after' pill too slow, she says

- Ricardo Alonso-Zaldivar, Los Angeles Times
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Washington -- The head of the Food and Drug Administration's women's health office resigned Wednesday in a widening protest over delays in deciding whether the "morning-after" contraceptive can be sold without a prescription.

Susan F. Wood, a biologist and veteran of 15 years in professional positions on Capitol Hill and in two administrations, took the unusual step of publicly announcing her resignation in an e-mail to friends and colleagues that was distributed to the media by a policy group that favors reproductive choice.

"I can no longer serve . . . when scientific and clinical evidence, fully evaluated and recommended for approval by the professional staff here, has been overruled," wrote Wood, 46, who has been at the agency nearly five years and held the title of assistant commissioner.

FDA Commissioner Lester Crawford had announced Friday that even though the drug is safe, proposed restrictions on teenage girls' access to it have raised legal issues that must be examined in a process that could take months, or longer. The FDA had earlier promised a decision by today.

Wood's resignation brought calls from prominent Democratic lawmakers for hearings into the agency's handling of the issue. Already under criticism for drug safety lapses, the FDA is now being drawn into a polarizing debate about reproductive choice and sexual mores.
Proponents of the drug, marketed as Plan B, say making it more easily available would prevent unwanted pregnancies and reduce the number of abortions. Opponents, including social conservatives in the Bush administration's political base, say it would encourage promiscuity, and they liken it to an abortion drug -- a position counter to the FDA's.
An FDA fact sheet about Plan B says it "works like other birth control pills to prevent pregnancy," and some outside medical advisers to the FDA said the agency has compromised its scientific reputation.
The FDA issued a one-paragraph statement calling Wood's decision "unfortunate." It said regulators had made "significant strides" under her leadership in protecting and advancing women's health.

Sen. Michael Enzi, R-Wyo., chairman of the Health, Education, Labor and Pensions Committee, is considering whether to hold hearings, said spokesman Craig Orfield. Enzi had expected "a firm decision" from the FDA, not further delays, Orfield said.

In an interview, Wood described herself as a "behind-the-scenes kind of person" who is not politically active.

"The reason I left is that if I'm going to be standing there as the face of women's health at the commissioner's level, to stand there quietly is to support (the FDA position) . . . and I really just couldn't do it," she said. Agency colleagues have called or stopped by to express support, Wood said. "There are people within FDA who are concerned the agency will lose credibility by the way (the Plan B) decision is being handled," she said.

A conservative group issued a news release applauding her resignation. "Thank goodness, there is now one less political activist at the FDA who puts radical feminist ideology above women's health," said Wendy Wright, policy director for Concerned Women for America.

But in a joint statement, Sens. Hillary Rodham Clinton, D-N.Y., and Patty Murray, D-Wash., said that "the FDA and the American people have lost a strong voice for scientific integrity in Dr. Wood."

Separately, in a letter to Enzi, they asked for formal hearings.
"A delay is not a decision, and no amount of semantics can change that," Clinton and Murray wrote. "It is time for the FDA to stop playing games with the health and well-being of millions of American women."
Plan B, made by Barr Laboratories, won FDA approval as a prescription drug in 1999. Its path to over-the-counter designation has been convoluted.

Last year, the FDA overruled an advisory panel recommendation and decided to keep Plan B as a prescription drug. But the agency invited Barr to re-apply after submitting additional data, and the company asked that the drug be made freely available to women 16 and older while younger girls would need a prescription. The FDA's Center for Drug Evaluation and Research has determined that the product can be safely sold without a prescription to women 17 and older.